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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1654	18

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/827,371	Hung
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 11, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 6-11, and 22-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 6-11, and 22-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of the single disclosed species, a nonabsorbable biocompatible solution, in Paper No. 15 is acknowledged. Acknowledgment is made of Applicant's listing of the claims readable thereon the elected invention of a nonabsorbable biocompatible solution, namely Claims 1, 6-11, 22, 24 and 25.

The claims have been examined, insofar, as they read on the elected invention, namely Claims 1 and 22. Please note that the Office does not consider that either claims 24 or 25 read on the elected species, since the elected species reads on "a nonabsorbable biocompatible solution" versus the agents of Claim 24 and 25, which do not read on a nonabsorbable biocompatible **solution.** Furthermore, upon further consideration, Claims 8-11 are not considered generic to the claimed invention, as set forth below.

Claims 1, 6-11 and 22-27 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 6-11 as amended remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant argues case law that the claims as set forth in the amendment filed September 9, 2002, does not constitute new matter. Applicant also argues the Office has rebutted its own assertion that no specific examples by acknowledging a specific example in the specification "administration of an agent, namely mannitol, that increases the secretion of retrievable fluid in one or more breast ducts." However, Applicant's arguments are not persuasive because the specification as originally filed provides only for a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1. Applicant's asserts that one of

ordinary skill in the art would clearly find support for an agent that increases secreted ductal fluid in a specification that specifically discloses an agent that increases fluid secretion in a duct, and further argues that the two grammatical forms express the same concepts: "It is axiomatic that secreted ductal fluid in a breast is ductal fluid that is the result of secretion into the breast duct." Applicant's arguments are not persuasive because the specification as-filed only refers to agents that increase fluid secretion from a breast duct epithelium, as set forth on page 4, lines 1-9.

Insertion of the above mentioned claim limitations have no support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable **secreted ductal** fluid from a breast wherein the agent is selected from the Markush group recited in Claim 1. There is only one exemplified method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising the administration of an agent, namely mannitol, that increases the secretion of retrievable fluid in one or more breast ducts of the patient. For example, Applicant specifically discloses on page 9, lines 13-17 of the instant specification: "Thus the intraductally administered agent can comprise, . . . e.g., . . . and an agent that increases fluid secretion from a breast duct epithelium." Nowhere does Applicant disclose the intraductal administration of an agent that increases **secreted ductal** fluid from a

breast duct. As amended, the recitation of newly amended Claim 1 makes it appear that the claimed method is drawn to a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient wherein the ductal fluid is already secreted since the agent that is administered "increases retrievable secreted ductal fluid from a breast" vs. a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally an agent that increases the secretion of ductal fluid from a breast duct, as demonstrated by Applicant on page 14, lines 23-25: "The objective of these experiments was to test the effects of the introduction of a solution containing mannitol on the secretion of fluid from the breast ducts of live rabbits." This is not sufficient support for the new genus "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim limitations still is considered to be the insertion of new matter for the above reasons.

As the above mentioned claim limitation could not be found in the present specification and despite Applicant pointing to page 5, lines 27-28 of the specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1, 6-11 and 22-27 as amended are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks adequate written description for the claimed invention in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing a method of treatment comprising the administration of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material or the method

of use thereof. In the instant case, on page 5, line 29 to page 6, line 11 of the specification, Applicant discloses the intraductal administration of a wash fluid comprising a biocompatible agent or solution, *e.g.*, a nonabsorbable fluid. The specification further discloses on page 6, lines 30 to page 7, lines 1-2, the advantages of using a nonabsorbable fluid in the instantly claimed method of treatment. However, other than the mere mention on page 6, lines 22-24, that "the invention provides administering a nonabsorbable fluid or a fluid that actually draws fluid to it, *e.g.*, an oncotic or osmotic fluid in the process of collecting fluid from the duct", Applicant fails to adequately describe as to what Applicant defines or considers as a "nonabsorbable biocompatible solution". For example, nowhere in the present specification does Applicant render a definition of the term "nonabsorbable biocompatible solution" or cite an example of the term thereof.

Thus, Claims 1, 6-11 and 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that Applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied, see Eli Lilly, 119 F. 3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1977).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-11 and 22-27 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered uncertain by the term "nonabsorbable compatible solution" because it is unclear as to the subject matter Applicant intends to direct the subject matter of the claimed invention. It is uncertain as to how one of ordinary skill in the art would not know how to interpret the metes and bounds of this limitation, since neither the claims nor the specification defines or apprises the meaning of the term. The lack of clarity renders the claim very vague and ambiguous.

Claim 7 is rendered vague and indefinite by the phrase "wherein the agent comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration" because it is unclear as to the subject Applicant intends to direct the invention. For instance, it appears that the claimed limitations are outside the scope of the recited Markush group of Claim 1, since it is uncertain as to whether any, if any, of the agents that increase retrievable secreted ductal fluid from a breast duct "comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Objections

Claims 8-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 8-11 fail to further the subject matter of independent Claim 1, that is, a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient because the claimed invention is a one-step process comprising the intraductal administration to a patient an agent that increases retrievable secreted ductal fluid from a breast because the claimed process steps of Claims 8-11 are directed to post-processing steps not required by Claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 10, 22, 25 and 27 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Falconer et al. (U), as evidenced by the teachings of Kartinos et al. (B) and Mullins (C).

Applicant claims a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is selected from the Markush group recited in Claim 1. Applicant further claims a method as in claim 1, further comprising collecting a portion of the increased retrievable secreted ductal fluid from the breast duct. Applicant further claims a method as in claim 8, further comprising a step of analyzing one or more of cells, fluid or other material in the breast duct after the retrievable secreted fluid has been increased and a portion of it has been collected. Applicant further claims a method wherein the agent is a nonabsorbable biocompatible solution. Applicant further claims a method wherein the agent is selected from the group consisting of polyethyleneglycol (PEG), malodextrin, dextran, and dextran 70. Applicant further claims a method of claim 1, wherein the agent is selected from the group consisting of a growth factor, oxytocin and prolactin.

On page 182, Column 2, lines 6-15, Falconer teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins). Falconer further

teaches removing and sampling alveolar tissue associated with the injected duct systems for water content determinations and Na+, K+ and Cl- and [14C]-lactose analysis, on page 184, Column 2, lines 29-33. In Table 1, Falconer shows that increasing the amounts of prolactin increased the water content of wet tissue in the treated mammary gland tissue. On page 184, Column 1, lines 13-19 bridging Column 2, lines 1-6, Falconer teaches *in vivo* intraductal injection of prolactin to a patient showed an increase [K+] of 10 mmol/kg wet tissue (see Table 3); whereas, *in vivo* intraductal administration of prolactin and ouabain an increase [Na+]. On page 182, Column 2, lines 14-19, Falconer teaches an increased extracellular water content of the ouabain-treated glands (*see* Table 3). Table 3 also shows an increased extracellular water content of the prolactin-treated glands, as well.

Falconer does not expressly teach his method for the intraductal administration of prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution) to a patient as a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. However, the method taught by Falconer is a one step process comprising the intraductal administration of the same ingredient, as disclosed by Applicant. Thus, a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted

ductal fluid, wherein the agent is a nonabsorbable biocompatible solution, from a breast duct is inherent to the method of treatment taught by Falconer.

The reference anticipates the claimed subject matter.

Claims 1, 6, 8, 10, 22, 25 and 27 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by Martyn et al. (V), as evidenced by the teachings of Kartinos et al. (B) and Mullins (C).

Applicant's claimed invention of Claims 1, 8, 10, 22, 25 and 27 was set forth above. Applicant further claims a method as in claim 1, wherein the agent is in a state selected from the group consisting of a non-liquid, a gel, an emulsion, a gas and a semi-solid.

Martyn teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins). The emulsion was prepared by sonicating an aqueous solution phase consisting of phosphate buffer saline containing bovine serum albumin and Blue Dextran with safflower oil (see page 323. Column 2, under *"Mammary intraductal injections"*. In Table 1, Martyn shows that glycerolipid synthesis in the mammary gland was significantly enhanced in the presence of insulin, corticosterone and prolactin; addition of prolactin stimulated acetyl-CoA carboxylase activity; prolactin together with insulin and

corticosterone stimulated activity of fatty acid synthetase; glucose-6-phosphate dehydrogenase was enhanced with prolactin injection. On page 326, Column 1, lines 9-27, Martyn teaches that intraductal injection of prolactin, or prolactin plus progesterone, had more secretion than did untreated emulsion treated or progesterone-treated glands within the same patient.

Martyn does not expressly teach his method for the intraductal administration of prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution) to a patient as a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. However, the method taught by Martyn is a one step process comprising the intraductal administration of the same ingredient, as disclosed by Applicant. Thus, a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient an agent that increases retrievable secreted ductal fluid, wherein the agent is a nonabsorbable biocompatible solution, from a breast duct is inherent to the method of treatment taught by Martyn.

The reference anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8-11, 22 , 25 and 27 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Falconer et al. (U) in view of Love (A).

Applicant's claimed invention of Claims 1, 8, 10, 22, 25 and 27 was set forth above. Applicant further claims a method as in claim 8, wherein collecting comprises accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device. Applicant further claims a method as in claim 10, wherein the step of analyzing comprises identifying a marker of a breast condition.

The teachings of Falconer was set forth above. Falconer teaches the claimed method except for wherein collecting comprises accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device; and, wherein the step of analyzing comprises identifying a marker of a breast condition. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed process steps to the method of treatment taught by Falconer to provide the claimed invention because Love teaches the intraductal administration of physiological saline to a breast

duct for the retrieval of fluid, cells and/or other material from a breast of a patient. In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced into the ductal network D_2 will be sufficiently large so that substantially the entire volume of the ductal network may be filled with the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed process step of accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device and the process step of analyzing comprises identifying a marker of a breast condition to the method taught by Falconer to provide the claimed invention because Falconer taches that the intraductal administration of a nonabsorbable biocompatible solution comprising dextran increases retrievable secreted ductal fluid and Love teaches that although physiological saline is a preferred washing fluid, other physiologically solutions such as the contrast media, *i.e.*,Dextran Blue, taught by Falconer may also be used, in Column 5, lines 61-64. One of ordinary skill in the art would have been further motivated and one would have had a high expectation of success to add the process steps taught by Love to the method of treatment taught by Falconer to provide the claimed method because in

Column 2, lines 21-32 and Column 3, lines 5-20, Love suggests that her method for obtaining fluids, marker substances and cellular material comprising the intraductal administration of fluids into the breast of a patient is minimally traumatic to the patient and provides a reliable and consistent method of obtaining cellular and non-cellular marker materials from the ductal networks in a breast to enable screening, diagnosis, and monitoring of disease conditions of the breasts. *See* Column 3, lines 22-65, also.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 6, 8-11, 22 and 25 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over Martyn et al. (V) in view of Love (A).

Applicant's claimed invention was set forth above.

Martyn teaches the claimed method except for wherein collecting comprises accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device; and, wherein the step of analyzing comprises identifying a marker of a breast condition. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the instantly claimed process steps to the method of treatment taught by Martyn to provide the claimed invention because Love teaches the intraductal administration of physiological saline to a breast duct for the retrieval of fluid, cells and/or other material from a breast of a patient. In Column 6, lines 55-67, Love discloses that "The volume of fluid introduced

into the ductal network D_2 will be sufficiently large so that substantially the entire volume of the ductal network may be filled with the washing fluid and excess fluid will flow from the network as it is displaced by additional fluid input . . . The remaining fluid will continue to be introduced and will thus flush the cellular and other marker materials from the ductal network into the opening . . ." After collection of the washing fluid comprising the retrievable fluid obtained from the breast duct through a double lumen catheter, Love teaches analyzing the fluid to identify a marker of a breast condition (see Column 5, lines 38-44). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed process step of accessing a breast duct with a device and withdrawing a portion of the increased retrievable secreted ductal fluid into the device and the process step of analyzing comprises identifying a marker of a breast condition to the method taught by Martyn to provide the claimed invention because Martyn taches that the intraductal administration of a nonabsorbable biocompatible solutions, *e.g.*, either aqueous or emulsified, comprising dextran increases retrievable secreted ductal fluid and Love teaches that although physiological saline is a preferred washing fluid, other physiologically solutions such as the contrast media, *i.e.*,Dextran Blue, taught by Martyn may also be used, in Column 5, lines 61-64. One of ordinary skill in the art would have been further motivated and one would have had a high expectation of success to add the process steps taught by Love to the method of treatment taught by Martyn to provide the claimed method because in Column 2, lines 21-32 and Column 3, lines 5-20, Love suggests that her method for obtaining fluids, marker substances and cellular material

comprising the intraductal administration of fluids into the breast of a patient is minimally traumatic to the patient and provides a reliable and consistent method of obtaining cellular and non-cellular marker materials from the ductal networks in a breast to enable screening, diagnosis, and monitoring of disease conditions of the breasts. *See* Column 3, lines 22-65, also.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-11 and 22-27 as amended remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 157-165 of copending Application No. 09/907,581. The rejection stands for the reasons set forth in the previous Office action and repeated below.

Applicant defers consideration of filing a terminal disclaimer until the determination of allowable subject matter by the Patent Office. Therefore, the rejection stands because: Although the conflicting claims are not identical, they are not patentably distinct from each other because the process steps, the actual ingredients, the subjects to which the ingredients are administered, and the claimed functional effect appear to be identical or essentially the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

September 30, 2003

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER